

This initiative measure is submitted to the People in accordance with the provisions of Article II, Section 8, of the California Constitution.

This initiative measure adds sections to the Health and Safety Code; therefore, new provisions proposed to be added are printed in *italic* type to indicate that they are new.

SEC. 1. Name

This Act shall be known as the "Protect the Lives of Dialysis Patients Act."

SEC. 2. Findings and Purposes

This Act, adopted by the People of the State of California, makes the following Findings and has the following Purposes:

A. The People make the following findings:

(1) Kidney dialysis is a life-saving process in which blood is removed from a patient's body, cleaned of toxins, and then returned to the patient. It must be done at least three times a week for several hours a session, and the patient must continue treatment for the rest of their life or until they can obtain a kidney transplant.

(2) In California, nearly 80,000 people undergo dialysis treatment.

(3) Just two multinational, for-profit corporations operate or manage nearly three-quarters of dialysis clinics in California and treat more than 75 percent of dialysis patients in the state. These two multinational corporations annually earn billions of dollars from their dialysis operations, including close to \$450 million a year in California alone.

(4) Studies have found that compared to patients at non-profit dialysis clinics, patients at for-profit clinics are less likely to get kidney transplants, more likely to be hospitalized, and more likely to die.

(5) Many dialysis clinics are operated as joint ventures between for-profit corporations and physicians. A physician who owns a stake in a dialysis clinic may also be serving as the kidney patient's primary doctor, creating a potential conflict of interest. More transparency is necessary for researchers to study the impact of physician ownership on patient care and whether these ownership interests influence decisions regarding dialysis care approaches, patients' choice of clinics, and when to start or discontinue dialysis.

(6) Dialysis patients can make better decisions about their own care when they are informed about whether their physician has an ownership interest in the clinic where they receive dialysis.

(7) The dialysis procedure and side effects from the treatments present several dangers to patients, and many dialysis clinics in California have been cited for failure to maintain proper standards of care. Failure to maintain proper standards can lead to patient harm, hospitalizations, and even death.

(8) Dialysis clinics are currently not required to maintain a doctor or other advanced practitioner on site to oversee quality, ensure the patient plan of care is appropriately followed, and monitor safety protocols. Patients should have access to a physician or advanced practitioner on site whenever dialysis treatment is being provided.

(9) Dialysis treatments involve direct access to the bloodstream, which puts patients at heightened risk of getting dangerous infections. Proper reporting and transparency of infection rates encourages clinics to improve quality and helps patients make the best choice for their care.

(10) When health care facilities like hospitals and nursing homes close, California regulators are able to take steps to protect patients from harm. Likewise, strong protections should be provided to vulnerable patients when dialysis clinics close.

(11) Dialysis corporations have lobbied against efforts to enact protections for kidney dialysis patients in California, spending over \$100 million in 2020 to influence California voters.

B. Purposes:

This Act is intended to:

(1) ensure that outpatient kidney dialysis clinics provide quality and affordable patient care to people suffering from end-stage renal disease;

(2) provide the government information it needs to supervise dialysis clinics to ensure all dialysis clinic owners and physicians provide patients with appropriate care;

(3) provide dialysis patients with information about dialysis clinics and physicians' financial interests so patients can make informed choices about their care; and

(4) be budget neutral for the State to implement and administer.

SEC. 3. Section 1226.7 is added to the Health and Safety Code, to read:

1226.7. (a) Chronic dialysis clinics shall provide the same quality of care to their patients without discrimination on the basis of who is responsible for paying for a patient's treatment. Further, chronic dialysis clinics shall not refuse to offer or to provide care on the basis of who is responsible for paying for a patient's treatment. Such prohibited discrimination includes, but is not limited to, discrimination on the basis that a payer is an individual patient, private entity, insurer, Medi-Cal, Medicaid, or Medicare. This section shall also apply to a chronic dialysis clinic's governing entity, which shall ensure that no discrimination prohibited by this section occurs at or among clinics owned or operated by the governing entity.

(b) For purposes of this section, the following definitions shall apply:

(1) "Chronic dialysis clinic" has the same meaning as in Section 1204.

(2) "Governing entity" means a person, firm, association, partnership, corporation, or other entity that owns or operates a chronic dialysis clinic for which a license has been issued, without respect to whether the person or entity itself directly holds that license.

SEC. 4. Section 1226.8 is added to the Health and Safety Code, to read:

1226.8. (a) Every chronic dialysis clinic must maintain, at the chronic dialysis clinic's expense, at least one licensed physician, nurse practitioner, or physician assistant present on site during all times that in-center dialysis patients are being treated. This on-site clinician shall have authority and responsibility over patient safety and to direct the provision and quality of medical care.

(1) The physician, nurse practitioner, or physician assistant present on site shall have at least 6 months of experience providing care to patients with end-stage renal disease.

(2) A chronic dialysis clinic may apply to the department for an exception to the requirement in subdivision (a) on the grounds that a bona fide shortage of qualified physicians, nurse practitioners, or physician assistants prevents it from satisfying the requirement. Upon such a showing, the department may grant an exception that permits the clinic to satisfy the requirement in subdivision (a) by having at minimum, at the chronic dialysis clinic's expense, a physician, nurse practitioner, or physician assistant available to provide care through telehealth at all times that in-center dialysis patients are being treated, provided that the telehealth clinician has at least 6 months of experience providing care to patients with end-stage renal disease.

(3) The duration of an exception granted by the department pursuant to paragraph (2) shall be one calendar year from the date the clinic is notified of the department's determination.

(b) For each chronic dialysis clinic, the clinic or its governing entity shall quarterly report to the department, on a form and schedule prescribed by the department, dialysis clinic health care associated infection ("dialysis clinic HAI") data, including the incidence and type of dialysis clinic HAIs at each chronic dialysis clinic in California and such other information as the department shall deem appropriate to provide transparency on dialysis clinic HAI infection rates and promote patient safety. The chief executive officer or other principal officer of the clinic or governing entity shall certify under penalty of perjury that he or she is satisfied, after review, that the dialysis clinic HAI report submitted to the department is accurate and complete. The department shall post on its website the dialysis clinic HAI data from this report, at the same level of detail as provided in the report. The posted information shall include information identifying the governing entity of each chronic dialysis clinic.

(c) A chronic dialysis clinic shall provide to patients a list of physicians who have an ownership interest or indirect ownership interest in the clinic totaling 5 percent or more. Disclosure of this information must be in writing and must be provided to patients when they begin receiving treatment at the clinic, annually thereafter, and at any other time at the patient's request, as well as to prospective patients at their request.

(1) For each chronic dialysis clinic, the clinic or its governing entity shall quarterly report to the department, on a form and schedule prescribed by the department, persons with an ownership interest or indirect ownership interest in the clinic totaling 5 percent or more, including percentage of ownership interest and nature of ownership interest. The department shall post on its website the forms submitted for each chronic dialysis clinic.

(2) For each chronic dialysis clinic, the governing entity shall post on its website the ownership form as submitted to the department.

(d) In the event the department determines that a chronic dialysis clinic or governing entity failed to maintain the information or timely submit a report required under this section, or that the report submitted was inaccurate or incomplete, the department shall assess a penalty against the chronic dialysis clinic or governing entity not to exceed one hundred thousand dollars (\$100,000). The department shall determine the amount of the penalty based on the severity of the violation, the materiality of the inaccuracy or omitted information, and the strength of the explanation, if any, for the violation. Penalties collected pursuant to this paragraph shall be used by the department to implement and enforce laws governing chronic dialysis clinics.

(e) For purposes of this section, the following definitions shall apply:

(1) "Chronic dialysis clinic" has the same meaning as in Section 1204.

(2) "Dialysis clinic HAI" means a bloodstream infection, local access site infection, or vascular access infection related to a dialysis event as defined by the National Healthcare Safety Network of the federal Centers for Disease Control and Prevention, or any appropriate additional or alternative definition that the department defines by regulation.

(3) "Governing entity" has the same meaning as in Section 1226.7.

(4) "Licensed physician" means a nephrologist or other physician licensed by the state pursuant to Chapter 5 of Division 2 of the Business and Professions Code.

(5) "Indirect ownership interest" means an ownership interest in a person or entity that has an ownership interest in the chronic dialysis clinic. This term includes an ownership interest in any person or entity that has an indirect ownership interest in the chronic dialysis clinic.

(6) "Nurse practitioner" means a registered nurse licensed pursuant to Chapter 6 of Division 2 of the Business and Professions Code and certified as a nurse practitioner by the Board of Registered Nursing.

(7) "Ownership interest" means an interest through equity, debt, or other means, including the possession of equity in the capital, stock, or profits of a chronic dialysis clinic; an interest in the revenue of a chronic dialysis clinic; partnership shares; limited liability company memberships; or an interest in any mortgage, deed of trust, note, or other obligation secured by a chronic dialysis clinic.

(8) "Person" means a natural person, firm, association, organization, partnership, business trust, company, joint stock company, corporation, limited liability company, joint venture, or other organizations of persons.

(9) "Physician assistant" means a physician assistant licensed pursuant to Chapter 7.7 of Division 2 of the Business and Professions Code.

SECTION 5. Section 1226.9 is added to the Health and Safety Code, to read:

1226.9. (a) Prior to closing a chronic dialysis clinic, or substantially reducing or eliminating the level of services provided by a chronic dialysis clinic, the clinic or its governing entity must provide written notice to, and obtain the written consent of, the department.

(b) The department shall have discretion to consent to, give conditional consent to, or not consent to, any proposed closure or substantial reduction or elimination of services. In making its determination, the department may take into account information submitted by the clinic, its governing entity, and any other interested party, and shall consider any factors that the department considers relevant, including, but not limited to, the following:

(1) The effect on the availability and accessibility of health care services to the affected community, including but not limited to the clinic's detailed plan for ensuring patients will have uninterrupted access to care.

(2) Evidence of good faith efforts by the clinic or governing entity to sell, lease, or otherwise transfer ownership or operations of the clinic to another entity that would provide chronic dialysis care.

(3) The financial resources of the clinic and its governing entity.

(c) For purposes of this section, the following definitions shall apply:

(1) "Chronic dialysis clinic" has the same meaning as in Section 1204.

(2) "Governing entity" has the same meaning as in Section 1226.7.

SEC. 6. Section 1226.10 is added to the Health and Safety Code, to read:

1226.10. (a) If a chronic dialysis clinic or governing entity disputes a determination by the department pursuant to Sections 1226.8 or 1226.9, the chronic dialysis clinic or governing entity may, within 10 working days, request a hearing pursuant to Section 131071. A chronic dialysis clinic or governing entity shall pay all administrative penalties when all appeals have been exhausted if the department's position has been upheld.

(b) For purposes of this section, the following definitions shall apply:

(1) "Chronic dialysis clinic" has the same meaning as in Section 1204.

(2) "Governing entity" has the same meaning as in Section 1226.7.

SEC. 7. Section 1266.3 is added to the Health and Safety Code, to read:

1266.3. It is the intent of the People that California taxpayers not be financially responsible for implementation and enforcement of the Protect the Lives of Dialysis Patients Act. In order to effectuate that intent, when calculating, assessing, and collecting fees imposed on chronic dialysis clinics pursuant to Section 1266, the department shall take into account all costs associated with implementing and enforcing Sections 1226.7 through 1226.10.

SEC. 8. Nothing in this Act is intended to affect health facilities licensed pursuant to subdivision (a), (b), or (f) of Section 1250 of the Health and Safety Code.

SEC. 9. (a) The State Department of Public Health is authorized to and, within one year following the Act's effective date, shall adopt regulations implementing Sections 1226.8 and 1226.9 of the Health and Safety Code to further the purposes of this Act.

(b) If the Department is unable to adopt the required final regulations within one year following the Act's effective date, the adoption of emergency implementing regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare, in which case the Department shall adopt initial emergency implementing regulations no later than one year following the Act's effective date, or as soon thereafter as is practicable. If such emergency regulations are adopted, the Department shall adopt the required final regulations by the time the emergency regulations expire.

SEC. 10. Pursuant to subdivision (c) of Section 10 of Article II of the California Constitution, this Act may be amended either by a subsequent measure submitted to a vote of the People at a statewide election; or by a statute validly passed by the Legislature and signed by the Governor, but only to further the purposes of the Act.

SEC. 11 (a) In the event that this initiative measure and another initiative measure or measures relating to the regulation of chronic dialysis clinics or the treatment and care of dialysis patients appear on the same statewide election ballot, the other initiative measure or measures shall be deemed to be in conflict with this measure. In the event that this initiative measure receives the highest number of affirmative votes, the provisions of this measure shall prevail in their entirety, and the provisions of the other initiative measure or measures shall be null and void.

(b) If this initiative is approved by the voters but superseded in whole or in part by any other conflicting ballot measure approved by the voters at the same election, and such conflicting measure is later held invalid, this measure shall be self-executing and given full force and effect.

SEC. 12. The provisions of this Act are severable. If any provision of this Act or its application is held invalid, that invalidity shall not affect the remaining portions of this Act or any application that can be given effect without the invalid provision or application. The People of the State of California hereby declare that they would have adopted this Act and each and every portion, section, subdivision, paragraph, clause, sentence, phrase, word, and application not declared invalid or unconstitutional without regard to whether any portion of this Act or application thereof would be subsequently declared invalid.